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Evaluation of clinical efficacy and safety of the Ilizarov apparatus for external fixation (literature review)

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Purpose A retrospective analysis of clinical efficacy and safety of using the external fixation apparatus of G.A. Ilizarov's design. **Materials and methods** Analysis and evaluation of clinical data was performed using 107 literary sources. 4.200 clinical cases were studied to evaluate effectiveness, and 6.274 cases to assess safety. **Results** The analysis revealed a high clinical efficacy of using the Ilizarov apparatus for external fixation (various assemblies) in solving a wide range of practical problems in the field of traumatology and orthopedics. According to the results of the study, its high clinical treatment effectiveness was confirmed both on the use of the method in general (about 95 % of positive outcomes), and in specific nosological groups of patients (not lower than 90 % of positive outcomes). After having assessed the available data on the safety in the application of the Ilizarov apparatus for external fixation (various assemblies), we can conclude that the rates of adverse events, recorded in the literature analyzed, can be considered acceptable. Among all those events, the events classified as adverse effects of the product amounted to 17.03 % (5 ÷ 95 % CI: 16.11 ÷ 17.97 %).
Keywords: Ilizarov apparatus, clinical efficacy and safety

INTRODUCTION

The external fixation apparatus developed by G.A. Ilizarov has been used in contemporary surgical practice and provides significant rates of positive results in the treatment of a wide range of pathology of the musculoskeletal system [1–3]. Technologies combining the Ilizarov apparatus with other methods have been also developed and are aimed at treating patients with orthopedic and traumatic pathologies [4–10].

Along with the accumulation of experience in the use of the external fixation apparatus, a number of problems were identified such as risks of developing joint contractures, vascular and neurological complications; "ischemic" regenerates; penetration of infectious agents along the structural elements of the external fixation apparatus that pass into the bone [11–22].

At present, the demand for the Ilizarov external fixation apparatus and its components for implementation of the technologies of transosseous osteosynthesis for treatment of patients with injuries and orthopedic pathology has been growing [23, 24].

Therefore, the goal of our study was to objectify clinical and management risks of using the Ilizarov apparatus. The study is devoted to assessing clinical efficacy and safety of the Ilizarov apparatus in practical traumatology and orthopedics.

MATERIAL AND METHODS

The analysis of clinical efficacy and safety was based on the literature reports that discuss the experience of using the Ilizarov external fixation apparatus.

Clinical Data Search Strategy A systematic search for data on the use of the Ilizarov apparatus was conducted in open electronic databases of scientific literature at PubMed and eLIBRARY platforms, as well as the collection of the Medical Library of the Federal State Budgetary *Institution Russian Ilizarov Scientific Center for Restorative Traumatology and*

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Orthopaedics of the Ministry of Health of Russia, the world's leading institution for clinical application of the Ilizarov transosseous osteosynthesis technologies.

The following keywords were used to search for clinical data: “transosseous osteosynthesis”, “apparatus”, “Ilizarov method”, “Ilizarov” (in Russian and English versions).

To analyze and evaluate the clinical data, the following criteria were defined for inclusion and exclusion of sources into the study.

Inclusion criteria:

1) full-text sources or structured abstracts with available specific quantitative data;

2) clinical studies stating that patients were treated using the Ilizarov transosseous osteosynthesis techniques or the Ilizarov method and/or apparatus;

3) sources that contain quantitative data on the evaluation of treatment results regarding its effectiveness and safety (the number of positive/ negative treatment outcomes, rating scales, number of complications, etc.), indicating the authors and/or the name of the rating systems and tests used.

Exclusion criteria:

1) studies in which transosseous osteosynthesis technologies were used in combination with other techniques;

2) clinical cases, pilot and preliminary studies;

3) "duplication" studies (a similar study protocol, similar groups and number of patients, a similar team of authors, etc.). If “duplicate” articles were found, a source with a more recent publication date was chosen.

Separately, scientific sources containing research data were analyzed that compared the effectiveness and safety of the clinical use of the Ilizarov apparatus for external fixation with other methods and technologies applied in orthopedics and traumatology.

Primary and secondary endpoints to evaluate product performance

Primary endpoints (rates of positive treatment outcomes at the time of dismantling the Ilizarov):

– bone consolidation;

– lengthening magnitude achieved as planned;

– defect/deformity correction;

– arthrodesis achieved;

– positive treatment outcomes according to clinical and functional rating scales.

Secondary endpoints (rates of positive outcomes at long term follow-up (more than one year after the dismantling of the device)):

– according to clinical and functional evaluation scales;

– treatment results preserved.

Endpoints for assessing product safety – rates of severe adverse events and adverse effects recorded during product performance.

The definition of adverse events and their categorization in this study is accepted in accordance with GOST R ISO 14155-2014 “Clinical studies. Good clinical practice” (paragraphs 3.1, 3.2, 3.15, 3.36, 3.37, 3.42).

The following grading was applied to evaluate the cause-effect relationship between the medical device and an undesirable event in this study: reliable, probable, likely, unlikely relationship or no relationship (Letter of health care inspection body *Roszdravnadzor* dated 28.12.2012 No. 04I-1310/12 “On the procedure of monitoring the safety of medical products in clinical trials ").

Prior to the study, a written approval was obtained from the institutional ethics committee. The study was conducted in accordance with ethical standards established in the Helsinki Declaration, applicable law and applicable regulatory requirements.

Mathematical analysis of retrospective data included a quantitative analysis of the results of previous studies, including data on the effectiveness and safety of the product. Quantitative primary and secondary criteria for evaluating the effectiveness and safety were summarized in tables and presented using descriptive statistics in the form of absolute and relative values (percentage of the total), 5÷95 percent confidence interval (5–95 % CI). Missing data are marked in the tables as “no data” and were not taken into account in general statistics.

RESULTS

Literature sources included in the study for the analysis of efficacy and safety, containing the data on primary and secondary endpoints, are presented in the list of references [25–131].

Data on efficacy All sources were grouped into four sections according to the pathology groups in accordance with the main purposes of the Ilizarov apparatus application formulated by the author himself:

– closed reduction and fixation of bone fragments in fractures and nonunion;

– operative and bloodless limb lengthening;

– correction of deformities and management of long bone defects without bone grafts;

– compression arthrodesis of large joints or elimination of stiff contractures.

Summarized findings on the efficiency of the Ilizarov external fixation apparatus are given in Table 1.

The results of the summary demonstrate that at the end of treatment (removal of the device, primary endpoint), the rates of positive outcomes in treating patients with pathologies of the musculoskeletal system using the Ilizarov apparatus ranged from 91.43 to 98.75 %, and at the time of a long term follow-up (secondary endpoint) they ranged between 90.91 and 100 %. Such fluctuations in the rates are associated with the features of the pathology for which the Ilizarov apparatus was used.

The summarized data on the efficiency of the Ilizarov apparatus showed the following:

– a total of 82 scientific literature sources were included into the study for the analysis and evaluation of clinical data according to the inclusion and exclusion criteria;

– 4,200 cases were included to calculate the rates of positive outcomes resulting from the treatment at the time of dismantling the device (primary endpoint);

– a total of 4,031 positive outcomes of treatment was recorded in the reports included (bone consolidation, planned elongation, defect bridging, deformity correction, arthrodesis were achieved; grading of clinical and functional rating scales: "fair result" and higher);

– clinical efficacy of the Ilizarov apparatus for external fixation at the time-point of its dismantling was 95.98 % (5 ÷ 95 % CI: 95.37 ÷ 96.55 %);

A total of 1,644 cases were analyzed to calculate the rate of positive treatment outcomes at long-term follow-ups (secondary endpoint);

– positive outcomes of treatment reported were 1,560 cases (bone consolidation and elongation preserved, bone integrity in the area of the defect, absence of deformity recurrence, fusion maintained in arthrodesis; grading of clinical and functional rating scales were “fair” and higher);

– clinical efficacy of the Ilizarov apparatus for external fixation in regard to treatment results preserved in the long term (more than one year after dismantling) was 94.89 % (5 ÷ 95 % CI: 93.77 ÷ 95.90 %).

Table 1

Summarized data on the efficacy of the Ilizarov apparatus for external fixation for treatment of patients with pathology of the musculoskeletal system

Product designation	Number of sources	Primary endpoint, number of positive results/total of cases; % [5÷95 % – CI]	Secondary endpoint, number of positive results/total of cases; % [5÷95 % – CI]
closed reduction and fixation of bone fragments in fractures and nonunion	31	1029/1112 92.54 % [90.92÷94.01]	720/751 95.87 % [94.33÷97.17]
operative and bloodless limb lengthening	9	475/481 98.75 % [97.56÷99.55]	48/48 100 % [98.01÷100]
correction of deformities and management of long bone defects without bone grafts	35	2335/2397 97.41 % [96.74÷98.01]	762/812 93.84 % [92.08÷95.39]
compression arthrodesis of large joints or elimination of stiff contractures	7	192/210 91.43 % [87.28÷94.83]	30/33 90.91 % [78.93÷98.17]
Total:	82	4031/4200 95.98 % [95.37÷96.55]	1560/1644 94.89 % [93.77÷95.90]

To further evaluate the effectiveness of the Ilizarov apparatus, sources that compared the effectiveness of the clinical application of the Ilizarov apparatus for external fixation with other methods and technologies used in orthopedics and traumatology were analyzed.

A total of 12 comparative studies were found.

The effectiveness of using the Ilizarov apparatus for external fixation did not significantly differ from the one shown for the methods compared in eight studies.

The merits of Ilizarov transosseous osteosynthesis technologies using the apparatus for various pathologies were shown in four works. In particular, the authors refer the following to the advantages of the treatment with the Ilizarov apparatus:

– a shorter inpatient stay [91];

– a shorter time of fracture union [94];

– a shorter time of temporal disability [81];

– lower financial costs for treatment and subsequent rehabilitation [128].

Safety data All sources were also grouped into four sections according to the groups of pathologies, in accordance with the main purposes:

– closed reduction and fixation of bone fragments in fractures and nonunion;

– operative and bloodless limb lengthening;

– correction of deformities and management of long bone defects without bone grafts;

– compression arthrodesis of large joints or elimination of stiff contractures.

Summarized data on groups of all the cases reported in the sources included in the study on the clinical use of the Ilizarov apparatus of external fixation that developed adverse events are given in Table 2.

The results presented in the Table show that the list of complications and adverse events and their incidence vary and depend on the pathology for which the Ilizarov apparatus was used.

Summarized data on all cases of adverse events reported in the sources included into the study that discuss the clinical use of the Ilizarov apparatus (in various configurations) for external fixation are given in Table 3.

Table 2

Summarized data on the safety of the Ilizarov apparatus for external fixation in the treatment of patients with pathology of the musculoskeletal system

Product designation	Number of sources	Adverse events (*AE*)	Severe adverse events (*SAE*)
closed reduction and fixation of bone fragments in fractures and nonunion	27	Number of cases: 2005, 569 AE found (28.38 %): • 365 (18,20 %) – WTI; • 94 (4,69 %) – WC; • 87 (4,34 %) – CC ; • 10 (0,50 %) – WB; • 9 (0,45 %) – ND; • 4 (0,20 %) – VD	Number of cases: 2055*, 45 SAE (2.19 %) found: • 41 (2.00 %) – osteomyelitis; • 3 (0.14 %) – death; • 1 (0.05 %) – DI
operative and bloodless limb lengthening	15	Number of cases: 1829, 697 (38.11 %) AE found, among them: • 295 (16.13 %) – CC • 215 (11.76 %) – WTI • 140 (7.65 %) – ND • 32 (1.75 %) – WC • 10 (0.55 %) – D/S • 4 (0.22 %) – WB • 1 (0.05 %) – VD	Number of cases: 1829, 4 (0.22 %) SAE found: • 4 (0.22 %) – osteomyelitis
correction of deformities and management of long bone defects without bone grafts	16	Number of cases: 2242, 588 (26.23 %) AE found, among them: • 258 (11.51 %) – WTI • 152 (6.78 %) – CC • 111 (4.95 %) – ND • 31 (1.38 %) – WC • 18 (0.80 %) – WB • 11 (0.50 %) – dermatitis • 7 (0.31 %) – VD	Number of cases: 2242, 15 (0.67 %) SAE found, among them: • 14 (0.62 %) – osteomyelitis; • 1 (0.05 %) – death
compression arthrodesis of large joints or elimination of stiff contractures	3	Number of cases: 148, 24 (16.22 %) AE found, among them: • 18 (12.16 %) – WTI • 3 (2.03 %) – WB • 2 (1.35 %) – ND • 1 (0.68 %) – CC	Number of cases: 148, one (0.68 %) SAE found: • 1 (0.68 %) – DI

Notes: Abr. adverse events (*AE*) and severe adverse events (*SAE*): D/S – dislocation, subluxation of joints; WTI – wire tract inflammation; DI – deep infection; CC – contractures; ND - neurological disorders; WC – wire cutting out of soft tissues; WB – wire/pin breakage; VD – vascular damage. * – difference in the number of cases is due to the fact that in a part of the works there is an analysis of only severe complications

Table 3

Summarized data on numbers of adverse events and severe adverse effects in clinical use of the Ilizarov apparatus for external fixation for treating various musculoskeletal pathology

Adverse events (*AE*)	Number	% from the total of cases [5÷95 % – CI]
wire tract inflammation	856	13,75 [12,91÷14,62]
contractures	535	8,60 [7,92÷9,31]
neurological disorders	262	4,21 [3,73÷4,72]
cutting of wires out of soft tissues	157	2,52 [2,15÷2,92]
wire/pin breakage	35	0,56 [0,39÷0,76]
vascular damage	12	0,19 [0,10÷0,31]
dermatitis	11	0,18 [0,09÷0,30]
dislocation, subluxation of joints	10	0,16 [0,08÷0,27]
Total (number of cases: 6224)	**1878**	**30,17 [29,04÷31,32]**
Severe adverse effects (*SAE*)		
osteomyelitis	59	0,94 [0,72÷1,19]
death	4	0,06 [0,01÷0,14]
deep infection	2	0,03 [0÷0,09]
Total (number of cases: 6274*)	**65**	**1,04 [0,80÷1,31]**

* – difference in the number of cases is due to the fact that in a part of the works there is an analysis of only severe complications

Adverse events analysis (*AE*) According to the results of the literature assessed by the study, the *AE* rate by using the Ilizarov apparatus of external fixation (in various configurations) was 30.17 % (5 ÷ 95 % CI: 29.04 ÷ 31.32 %). Assessing the interconnection of the AEs with the use of the Ilizarov apparatus listed above, only one event was rated as "no relationship". It is dislocation and subluxation of the joints, which develops in the patients violating treatment regimen and neglecting the requirements of osteosynthesis.

The relationship of the remaining cases with the functioning of the apparatus was evaluated by us as reliable, probable and likely.

Cases of wire tract soft tissue inflammation, cutting of wires through soft tissue, vascular damage, wires/pins breakage have a reliable relationship with the use of the product and are qualified as adverse effects (*ADE*). Obviously, all these events are the result of the contact of the elements of the apparatus with tissues and organs of the body. All these AE arise due to errors in the Ilizarov apparatus maintenance (improper sterilization preparation, insufficient treatment of the parts after the apparatus was applied while changing dressings, non-observance of personal hygiene, etc.). Clinical experience presented in the sources studied shows that all *AE*s of this group can be managed without dismantling the device in almost 100 % of cases by using antibiotics and/or wire reinsertion. All the authors of the works analyzed by us pointed out that these events did not affect the final result of treatment. If the inflammatory process in the tissues surrounding the wires remains untreated, according to generalized experience, the process may aggravate and result in osteomyelitis (see *SAE* analysis).

Cases of dermatitis are probably associated with the product use, as it can be assumed that the cause of this event could be a lack of proper skin care, disease recurrence or predisposition to it.

Contractures and neurological disorders have a likely relationship with the use of the product; therefore, qualifying them as *ADE* is not entirely correct. Clinical experience shows that these events can indeed be the result of the injuries to the muscles and/or nerves with the parts of the product in contact with them. However, these cases mostly happen due to inadequate clinical post-operative care of the patients with the Ilizarov apparatus on (inadequate pharmacotherapy, lack of exercise therapy, physiotherapy, etc.). They can be completely corrected applying appropriate procedures or proper medication. These events, when corrected before apparatus dismantling, as shown by overall experience, do not affect the outcome of treatment either.

Thus, if we exclude from the general statistics those *AE*, the relationship of which with the performance of the product is not obvious (dermatitis, contractures, neurological disorders, dislocations and subluxations), we can calculate the number of *ADE* resulting from the impact of the Ilizarov apparatus: 1060 cases of *ADE* out of the total 6,224 which is 17.03 % (5 ÷ 95 % CI: 16.11 ÷ 17.97 %).

Severe adverse effects analysis (*SAE*) According to the results of the study, the SAE rates by application of the Ilizarov apparatus (in various configurations) was 1.04 % (5 ÷ 95 % CI: 0.80 ÷ 1.31 %).

Lethal outcomes were associated with cardiovascular diseases (2 cases), exacerbation of liver diseases (one case), one death happened as a result of acute massive blood loss in a patient with a gunshot injury. Obviously, all the *SAE*s listed were not associated with the use of the Ilizarov apparatus but with concomitant diseases, or due to the severity of the primary injury.

Cases of osteomyelitis and deep infection of tissues, as shown by the experience of the clinical use of the Ilizarov external fixation apparatus, develop due to the lack of treatment of soft tissue inflammation in the area of the wires. Therefore, it is not correct to qualify cases of osteomyelitis and deep infection of tissues as a severe adverse effect of the product itself (*SADE*).

To further evaluate the safety of the Ilizarov apparatus, we analyzed sources containing research data that compared the clinical safety of the Ilizarov apparatus of external fixation with other methods and technologies used in orthopedics and traumatology.

A total of 12 comparative studies were found.

Incidence of adverse events and osteomyelitis with the use of the Ilizarov external fixation apparatus did not statistically significantly differ from the compared methods in 10 studies.

Statistically significant differences were found between several safety indicators in the use of transosseous osteosynthesis technologies implemented with the Ilizarov apparatus in two papers. In particular, the authors of one report [115] observed a lower incidence of deep infection by using the Ilizarov apparatus relative to the monolateral fixator. In another study [73], it was found that the rate of unplanned hardware removal of the Ilizarov apparatus elements was significantly lower than that of internal fixators.

Thus, the safety analysis of the Ilizarov apparatus for external fixation used in various configuration showed the following quantitative characteristics:

– rate of adverse events (*AE*): 30.17 (5 ÷ 95 % CI: 29.04 ÷ 31.32 %);

– rate of adverse effects of the product (*ADE*): 17.03 % (5 ÷ 95 % CI: 16.11 ÷ 17.97 %);

– rate of severe adverse effects (*SAE*): 1.04 % (5 ÷ 95 % CI: 0.80 ÷ 1.31 %).

DISCUSSION

The analysis of the clinical data shows high efficiency of transosseous osteosynthesis technology, implemented through the use of the Ilizarov external fixation apparatus for solving a wide range of clinical problems in the field of traumatology and orthopedics. According to the results of the study, the high clinical efficacy of treatment was confirmed both in regard to the total of cases treated (about 95 % of positive outcomes) and in separate nosological groups (not lower than 90 % of positive outcomes). Clinical data prove that the Ilizarov apparatus provides all the qualities claimed: reduction and fixation in open and closed bone fracture repair as well as compression and distraction forces on bone fragments for various orthopedic tasks.

Comparative studies demonstrate that the effectiveness of treating patients with an orthopedic diseases and injuries using the Ilizarov apparatus for external fixation is not lower than with other methods, and according to certain parameters the product has significant (statistically significant) effectiveness in separate clinical groups, including the economic factor.

The rate of treatment failures using the Ilizarov apparatus can be estimated at 4 to 5 % according to the analysis of available sources. Failures are associated with relapses of pathologies. These are severe injuries and bone infection (mainly osteomyelitis and infected fractures), congenital defects and systemic abnormalities. Given these circumstances, we can consider this amount of poor results in patients with an orthopedic diseases and injuries treated with the Ilizarov apparatus for external fixation acceptable.

Given the available safety data of the technology of transosseous osteosynthesis, implemented through the use of the Ilizarov apparatus for external fixation (in various configurations), we can conclude that the incidence of *AE* and *SAE* recorded according to the analysis can be considered acceptable due to the following factors:

– among all *AE*s, the incidence of product adverse effect (*ADE*) is 17.03 % (5 ÷ 95 % CI: 16.11 ÷ 17.97 %);

– all adverse events are predictable, due to the long experience accumulated in using the Ilizarov apparatus;

– most of the *AE*s, if they are timely eliminated, practically do not affect the final result of treatment;

– considerable experience has been accumulated in prevention and elimination of all *AE*s, most *AE*s are stopped without dismantling the device [132, 133];

–incidence of AE decreases with the accumulation of both individual and collective experience in using the Ilizarov apparatus for external fixation [134, 135].

Product safety can be rated as very high. So, among all *AE* cases, the percentage of wire/half-pin breakage (the only *AE* that can be associated with safety) was only 0.56 % (5 ÷ 95 % CI: 0.39 ÷ 0.76 %). None of the analyzed sources indicate that the parts used to assemble the Ilizarov apparatus for external fixation were unstable to sterilization.

CONCLUSION

Thus, the analysis and evaluation of the data on the application of the Ilizarov apparatus for external fixation allows us to conclude that its efficacy is quite high; the emerging clinical risks are acceptable and can be eliminated.

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